QDx Instacheck™ Ferritin

INTENDED USE

QDx Instacheck™ Ferritin along with **QDx Instacheck™ Reader** is a fluorescence immunoassay that quantifies concentration of Ferritin in human serum and plasma.

INTRODUCTION

Ferritin, a major iron storage protein, is essential to iron homeostasis and is involved in a wide range of physiologic and pathologic processes. Ferritin makes iron available for critical cellular processes while protecting lipids, DNA, and proteins from the potentially toxic effects of iron. In clinical medicine, ferritin is predominantly utilized as a marker of total body iron stores. In cases of iron deficiency and overload, serum ferritin serves a critical role in both diagnosis and management. It is clear that low ferritin values less than reference range are usually representative of body iron deficiency. Recent study suggests that ferritin provides a more sensitive, specific and reliable measurement for determining iron deficiency at an early stage. On other hand, patients with ferritin levels that are higher than the reference range may be indicative of conditions such as iron overload, infections, inflammations, collagen diseases, hepatic diseases, neoplastic disease and chronic renal failure.

PRINCIPLE

QDx Instacheck™ Ferritin is based on fluorescence immunoassay technology. **QDx Instacheck™ Ferritin** uses a sandwich immuno-detection method, such that by mixing the detection buffer with serum / plasma specimen in a test tube, the fluorescence-labeled detector anti-ferritin antibody in buffer binds to ferritin antigen in serum / plasma specimen. As the sample mixture is loaded onto the sample well of the test cartridge and migrates through the nitrocellulose matrix of test strip by the capillary action, the complexes of detector antibody and ferritin are captured by the anti-ferritin sandwich pair antibody that has been previously immobilized on the test strip. Thus, the more ferritin antigen is in the serum / plasma specimen, the more complexes are accumulated on test strip. The signal intensity of fluorescence of the detector antibody reflects amount of ferritin captured and is processed from **QDx Instacheck™ Reader** to show ferritin concentration in the serum / plasma specimen. The default result unit of **QDx Instacheck™ Ferritin** is displayed in unit of ng/mL on **QDx Instacheck™ Reader**. The working range and the detection limit of **QDx Instacheck™ Ferritin** are 10-1,000 ng/mL and 4.51 ng/mL respectively.

* **Reference Range: 30-350 ng/mL for male**

20-250 ng/mL for female.

(It is recommended that each laboratory establishes its own reference range from the population of interest.)

COMPONENTS AND REAGENTS

QDx Instacheck™ Ferritin consists of a test cartridge, a detection buffer and an ID chip. The test cartridge is individually sealed with a desiccant in an aluminum pouch, and the detection buffer is dispensed individually in a tube. A box containing the pre-dispensed tubes is delivered separately from the test cartridge in a styrofoam box filled with ice packs.

- Test cartridge contains a test strip in which anti-ferritin antibody and keyhole limpet homocyanin (KLH) have been immobilized on the test and on the control and line of strip, respectively.
- Detection Buffer contains fluorescence-labeled anti-ferritin antibody, mouse-IgG, fluorescence-labeled anti-KLH antibody, BSA as a stabilizer, and sodium azide as a preservative in PBS.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this insert as well as the **QDx Instacheck™ Reader** operation manual.
- Lot numbers of all the test components (test cartridge, ID chip and detection buffer tube) must match with each other.
- Neither interchange the test components form different lots nor use the test components beyond expiration date.
- Test performed by using any test component of mismatching lot number or that beyond the expiration date may yield misleading test result(s).
- **QDx Instacheck™ Ferritin** is compatible only with **QDx Instacheck™ Reader**.
- The test cartridge should remain sealed in its original pouch until just prior to use. Do not use the test cartridge should it be damaged or the pouch found already opened.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- **QDx Instacheck™ Ferritin** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, **QDx Instacheck™ Reader** may produce minor vibrations which should be regarded as normal.
- A detection buffer tube should be used for processing one test sample only. Similarly a test cartridge should be used for testing one processed test sample only. Both the detection buffer tube as well as the test cartridge should be discarded after single use.
- Being potentially infectious, used tip(s), detection buffer tube(s) and test cartridge(s) should be handled carefully and disposed of by appropriate method in accordance with relevant local regulations.
- Sodium azide is not likely to be a human health hazard in the quantity present in the detection buffer. Generally, exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.

STORAGE AND STABILITY

- The test cartridge is stable for 20 months (while sealed in the aluminum foil pouch) if stored at 4-30°C.
- The detection buffer dispensed in the detection buffer tube is stable for 20 months if stored at 2-8°C.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- Do not remove the test cartridge from the aluminum foil pouch until just prior to use.
- After the test cartridge pouch and the detection buffer tube are opened, the test should be performed within 30 minutes.

LIMITATIONS OF THE TEST SYSTEM

QDx Instacheck™ Ferritin provides accurate and reliable test results subject to the following constraints:

- The result of **QDx Instacheck™ Ferritin** should be evaluated with all clinical and laboratory data available. If ferritin Test results do not agree with the clinical evaluation, additional tests should be performed.
- The false positive results include cross-reactions with some components of serum / plasma from individual to antibodies, and non-specific adhesion of some components in serum / plasma that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of ferritin antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
- Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in **QDx Instacheck™ Ferritin** and thus should not be used.
- Since the flow characteristic on nitrocellulose membrane and related test result are influenced by temperature and relative humidity, controlled testing environment is required for the best test results. To obtain best test result, check 'Note' in procedure section.
- Other factors may interfere with **QDx Instacheck™ Ferritin** and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

SAMPLE COLLECTION AND PROCESSING

The test can be performed on serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change test values.

MATERIALS SUPPLIED

REF **IFPC-7**

Components of QDx Instacheck™ Ferritin

- **Test Cartridge Box:**
  - Test Cartridges 10
  - ID Chip 1
  - Package Insert 1
- **Detection Buffer Box *:**
  - Detection Buffer Tubes 10

(*Box containing the detection buffer tubes is supplied separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.)

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Ferritin**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader** REF FPRR010
- Thermal Printer

TEST SETUP

1. Check the components of **QDx Instacheck™ Ferritin**: Sealed Test Cartridge, ID Chip, Detection Buffer Tube.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep the test cartridge and detection buffer tube at room temperature for at least 30 minutes just prior to performing the test. Place the cartridge on a clean, dust-free and flat surface.
4. Turn on power supply of the **QDx Instacheck™ Reader**.
5. Insert the ID chip into the 'ID Chip Port' of the **QDx Instacheck™ Reader**.
6. Press 'Select' button on the **QDx Instacheck™ Reader**. (*Please refer to the '**QDx Instacheck™ Reader** Operation Manual' for complete information and operating instructions.*)

TEST PROCEDURE

[Single mode]

※ **Note: Best test result comes out when the testing environment is at around 25°C temperature, 40% relative humidity.**

1. Transfer 30 µL of the serum or plasma sample using a transfer pipette to the tube containing the detection buffer**.** For performing a quality control test, pipette out 30 µL control standard reagent instead of serum or plasma sample and transfer it to the detection buffer tube.
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.
4. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
5. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process .
6. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge after 10 minutes.
7. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

※ **Note: Best test result comes out when the testing environment is at around 25°C temperature, 40% relative humidity.**

1. Transfer 30 µL of the serum or plasma sample using a transfer pipette to the tube containing the detection buffer**.** For performing a quality control test, pipette out 30 µL control standard reagent instead of serum or plasma sample and transfer it to the detection buffer tube.
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.

4. Leave the sample-loaded test cartridge at room temperature for 10 minutes.
5. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
6. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
7. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
8. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays Ferritin concentration of the test sample in terms of ng/mL.

QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control reagents are not provided with **QDx Instacheck™ Ferritin**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited.**
- **Internal Control**: **QDx Instacheck™ Ferritin** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. **Analytical Sensitivity**: **QDx Instacheck™ Ferritin** was evaluated on the limit of detection. Three different lots of Cartridges were evaluated with 10 times of each lot. Minimum detection was calculated by average of specimens (0 at value) + 3SD. The limit of **QDx Instacheck™ Ferritin** was determined to be 4.51 ng/mL.

2. **Specificity/Interference:** Some bio-molecules such as heterophilic antibodies consist of both natural antibodies and autoimmune antibodies that exhibit weak binding and polyspecificity, bilirubin, hemoglobin, triglycerides, and cholesterol may interfere with the measurement.

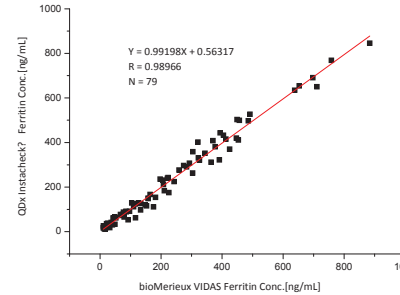
3. **Precision**: For the intra-assay imprecision, 20 replicates were tested at each control sample. For the inter-assay imprecision, tests were conducted on 10 sequential days, with 10 runs per day and with 10 replicates at each ferritin concentration.

Imprecision of QDx Instacheck™ Ferritin						
Ferritin (ng/mL)	Intra-assay			Inter-assay		
	Mean	SD	CV (%)	Mean	SD	CV (%)
15	14.89	0.97	6.54	15.16	0.94	6.22
150	149.11	4.08	2.73	149.73	1.80	1.20
450	451.32	7.95	1.76	451.53	7.11	1.58

(SD = Standard Deviation, CV = Coefficient of Variation)

4. **Linearity**: The high concentration was diluted with the low concentration to the following final percentages; 100%, 50%, 25%, 12.5%, 6.25%, 3.125%, 1.56%, 0.78%. Sample was assayed in triplicate in one analytical run at each ferritin level. The coefficient of linear regression was R^2=0.986. Linearity of **QDx Instacheck ™ Ferritin** was 7.8 ~ 1,000 ng/mL.

5. **Comparability (Correlation):** Ferritin concentrations of 79 clinical specimens were quantified independently with **QDx Instacheck™ Ferritin** and the BioMerieux mini-Vidas system according to the established standard test procedure. The test results were analyzed and their comparability was investigated with linear regression and correlation coefficient (*R*). The value of correlation of coefficient was 0.98966 between two methods.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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